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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,664	10/14/2003	Timothy Kershenstine JR.	K03-0197	3401

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,664

Applicant(s)

KERSHENSTINE, TIMOTHY

Examiner

Michele Flood

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a stable dietary supplement composition containing herbal ingredients selected from a group consisting of Spica Prunella Flos, Chrysanthemi Flos, Lonicera Japonica, Radix Notoginseng, Cleistocalyx Operculatis, Lentinus Edodes and Sophora Japonica, classified in class 424, subclass 725.
- II. Claims 8-10, drawn to a stable dietary supplement composition for decreasing and maintaining normal blood pressure in humans comprising as active ingredients claim-designated percentage amounts of herbal ingredients, classified in class 514, subclass 783.
- III. Claims 11-12, drawn to a stable dietary composition for lowering high blood pressure, the composition containing an effective amount of active ingredients selected from a group of claim-designated herbal ingredients, classified in class 514, subclass 2 or class 514, subclass 783, for example.
- III. Claims 13-14, drawn to a method of reducing blood pressure levels in humans comprising the daily administration of a composition containing as active ingredients claim-designated herbal ingredients, classified in class

424, subclass 728 or subclass 745 or subclass 757 or subclass 757 or subclass 773 or subclass 778.

- IV. Claims 15-16, drawn to a dietary supplement in tablet form comprising claim-designated percentage amounts of herbal ingredients, classified in class 424, subclass 464.
- VI. Claim 17, drawn to a dietary supplement in capsule form comprising claim-designated percentage amounts of herbal ingredients, classified in class 424, subclass 451.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the four different groups are directed to four different inventions. Different compositions comprising different ingredients do not necessarily have the same functional effect. Moreover, these compositions are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects.

Inventions I-II, IV-VI and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for

using the product as claimed can be practiced with another materially different product. For instance, in EP 284395 a, Kamishiro et al. teach an antihypertensive composition comprising a glycerol derivative, which is administered to humans to lower blood pressure in a subject in need thereof.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

This application also contains claims directed to numerous patentably distinct species of pharmaceutical compositions, said species containing numerous permutations of numerous ingredients. See claims 1 and 11.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of composition or single disclosed combination of species of composition, specifically stating which botanical group member, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is **also** required, in addition to electing a single disclosed botanical group member of a composition or combination of single disclosed botanical members of a composition as discussed above, to **also** elect under 35 U.S.C. 121 a single disclosed species of composition, **enumerating all ingredients present therein**, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Please note this requirement is made with particular regard to claims 1 and 11. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele Flood
MICHELE FLOOD
PATENT EXAMINER

MCF

November 15, 2004